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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MICHAEL J. HELLER

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EXAMINER

FORMAN, BETTY J

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/358,788	Applicant(s) HELLER ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,57,58 and 79-81 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 49,57,58 and 79-81 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

SUPPLEMENTAL DETAILED ACTION

Comment

This supplemental action is provided to correct paragraph 5 of the Office Action mailed 24 August 2010. The paragraph incorrectly omitted Claims 80 and 81 from the rejection. The paragraph has been corrected to include the omitted claims. The remaining text of the Office Action is unchanged.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 August 2010 has been entered.

Status of the Claims

2. This action is in response to papers filed 16 August 2010 in which claims 47, 58-59 and 79 were amended and claims 80-81 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 20 April 2010 under non-statutory double patenting, under 35 U.S.C. 112, first paragraph and under 35 U.S.C. 103(a) are withdrawn in view of the amendments.

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Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 49, 57-58 and 79-81 are under prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 49, 57, 58 and 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al (U.S. Patent No. 5,846,708, filed 23 April 1992) and Cozzette et al (U.S. Patent No. 5,063,081, issued 5 November 1991).

Regarding Claims 49 and 79-81, Hollis teaches a method for analyzing a sample oligonucleotide, the method comprising forming a plurality of test sites on a substrate (Column 4, lines 32-45, Fig. 1,4) wherein each test site is electronically addressable (Column 5, lines 6-18). Hollis further defines the electrodes in microns (Column 6, lines 1-5) thereby providing microelectrodes as claimed.

Hollis teaches electronically immobilizing oligonucleotide anchor sequences to individually selected locations (Column 13, lines 8-63), contacting the sample

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oligonucleotide with the immobilized probe for hybridization and subjecting the hybrids from to a reverse bias potential to remove unbound oligonucleotides (Column 13, line 64-Column 14, line 19) and detecting hybridization (Column 4, lines 46-67).

Hollis further teaches facilitating hybridization by addressable application of electrical potential (Column 13, line 62-Column 14, line 26).

The **electrically addressable test site** array of the invention also provides the ability to electronically induce or catalyze a synthesis reaction **in a given well**, or row, or column of wells, by **applying an electrical potential to the electrodes of such well** or wells.

The potential can be used to attract chemical reactants from solutions disposed near the wells and/or to catalyze a specific chemical reaction in the wells.

Furthermore, the hybridization between target molecular structures and completed probes can be enhanced by the application of an electrical potential to the electrodes just after the target solution is applied to the test sites. Without the application of a potential, the target molecular structures must diffuse through the solution to the probes. Due to the inefficiency of such a diffusion process, one must allow typically 1.5 to 2 hours for significant hybridization to take place, and even then a substantial number of probes remain unhybridized. An **electrical potential can draw charged target structures directly to probes near to or attached to the electrodes**, increasing both the rate of hybridization and the total number of target/probe hybridizations that can be conveniently produced in a given experiment. **Conversely, a reverse biased potential can be subsequently applied to aid in the washing (removal) of unhybridized and mismatched target molecules**. This technique is not only applicable to the electronic genosensors of FIGS. 1 through 9, which have electrodes present within each test site, but can be employed in both the micromechanical-resonator and CCD-based approaches by either using the electrodes present within or under each test site or fabricating one or more additional electrodes at each test site for this purpose.(emphasis added)

Hollis specifically teaches addressable application of electrical potential to “draw charged target” to the electrodes. Hollis further teaches that the same method is used

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to in an opposite manner ("Conversely") to remove unhybridized and mismatched targets. Hence, targets are removed at selected locations as claimed.

Hollis does not teach a selectively permeable layer and adjacent attachment layer. However, selectively permeable layers (permselective) between electrodes and the attachment layer were well known in the art at the time the invention was made as taught by Cozzette (Abstract).

Cozzette teaches a method similar to that of Hollis comprising immobilizing a binding partner (e.g. DNA) onto one of a plurality of electrodes, contacting with the complementary binding partner and detecting the interaction (Column 52, lines 4-20). Cozzette further teaches the method includes adding a probe complementary to a portion of the target that is not hybridized to the immobilized probe in a sandwich format and detecting formation of the sandwich (Column 52, lines 11-15).

Cozzette further teaches the electrode has a permselective layer and attachment layer made from aminopropyltriethoxy silane (§ 5.1.2) and teaches that the layer acts as a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest. Cozzette also teaches that the permselective layer also acts as an adhesion promoter for the attachment layer thereby facilitating biomolecule immobilization (paragraph spanning columns 13-14). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the permselective and attachment layers of Cozzette to the electrodes of Hollis. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the teachings of Cozzette. The artisan would have

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been further motivated to do so for the expected benefits of providing a barrier against interfering ionic species while allowing transport of smaller detectable moieties of interest and facilitating biomolecule immobilization as desired in the art (Cozzette, paragraph spanning columns 13-14).

Regarding Claim 57, Hollis teaches the method further comprising subjecting the oligonucleotide to a field to attract it to the immobilized probe (Column 14, lines 6-14).

Regarding Claim 58, Hollis teaches the method wherein the probe is 6 to 100 bases (Example 1, Column 16, line 10).

Response to Arguments

5. Applicant acknowledges that Hollis teaches an array of addressable electrodes but argues that the reference does not teach or suggest the newly claimed permeation layer. The argument has been considered but is not found sufficient to overcome the new grounds for rejection based on the teachings of Cozzette.

Applicant asserts that Hollis does not use the electrodes to control hybridization. The argument has been considered however as cited above. Hollis clearly teaches addressable application of electrical potential to attract analytes to the electrodes and "[C]onversely" remove unhybridized targets. It is maintained that Hollis teaches the electronically controlled hybridization as claimed.

Conclusion

6. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
Art Unit 1634

/BJ Forman/
Primary Examiner, Art Unit 1634